

### **Remarks**

Claims 19-29 and 33-36 were withdrawn from further consideration as being drawn to a non-elected species. Claims 24-27 are herein canceled. New claims 37-40 have been added and, based on the Examiner's withdrawal of claims, are herein withdrawn by the Applicant. Applicant reserves the right to rejoin withdrawn claims 33-40 upon the allowance of any claims from which these claims depend.

### **35 U.S.C. 102 Rejections**

#### **Smit USPN 4,315,509**

Claims 30-32 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Smit USPN 4315509.

Claim 30 of Applicant's invention teaches a storage that bulges relative to both a first tube connected to the storage at its up-stream opening and a second tube connected to the storage at its down-stream opening. Applicant finds no disclosure of the claimed invention in Smit and no support has been provided that adequately indicates Smit discloses what the claimed invention teaches.

The Examiner has submitted that Smit discloses in figures 1-2 a synthetic stomach comprising a storage, two tubes for connection to the esophagus and small intestine, and fixing means. While Applicant does not concede that Smit makes such a disclosure, Applicant submits that such a disclosure would not, if disclosed, anticipate the claimed storage because it does not recite a structure wherein a first tube is connected to a storage at the up-stream opening of the storage, a second tube is connected to the storage at the down-stream opening of the storage, and that the storage bulges relative to each of the connected tubes.

Smit discloses an extremely thin-walled tube that may be implanted to restrict absorption and an insertion and removal device in the form of a catheter for insertion and removal of the extremely thin-walled tube. This disclosure does not anticipate the claimed invention because it does not recite all of the structural elements of claim 30.

Claims 31-32 depend from claim 30 and are patentable over Smit for at least the same reasons that claim 30 is patentable over Smit.

Wilkinson USPN 5,246,456

Claims 30-32 also stand rejected under 35 U.S.C. 102(b) as being anticipated by Wilkinson USPN 5246456.

The Examiner has indicated that Wilkinson discloses in figures 1-8 a synthetic stomach comprising a storage, two tubes for connection to the esophagus and small intestine, fixing means and that the stomach storage bulges relative to the tubes.

Applicant submits that Wilkinson neither teaches nor suggests a storage comprising two tubes. Wilkinson teaches a pouch wherein the stomach is wrapped. The pouch “is preoperatively constructed of a predetermined size” and “is then secured about the stomach” (col. 1 line 66- col. 2 line 2).

Figs. 1 and 3 show the gastric pouch applied to the stomach of a patient; however, the pouch illustrated does not comprise two tubes as further demonstrated in Fig. 3, which shows an enlarged view of the collar of the pouch having no tube connected to it.

Figs. 4 -7 illustrate the construction of the pouch. To construct the pouch a mandrel 50 is provided in the desired shape of the pouch. The mandrel 50 is dipped repeatedly until an adequately thick layer of elastomer has been deposited on the metal mandrel 50. The metal mandrel is not a part of the elastomer pouch as demonstrated by the removal of the pouch from the mandrel (“the pouch is cut from around the neck of the mandrel” col. 4 lines. 63-64).

Fig. 8 illustrates a completed pouch, which does not comprise two tubes.

As Wilkinson does not disclose a storage having two tubes, Wilkinson does not anticipate the claimed invention.

Claims 31-32 depend from claim 30 and are patentable over Wilkinson for at least the same reasons that claim 30 is patentable over Wilkinson.

**35 U.S.C. 103 Rejections**

**Smit in view of Crabb**

Claim 31 stands rejected under 35 U.S.C. 103 (a) as being unpatentable over Smit USPN 4315509 in view of Crabb USPN 4315509.

The Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Smit to include rigid components as taught by Crabb. However, the Examiner has not clearly articulated any one of the seven rationales set forth in *KSR International Co. v. Teleflex Inc. USPQ2d 1385 (2007)* (KSR) and enumerated in MPEP 2143 to provide support for the conclusion that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Smit to include rigid components as taught by Crabb. Additionally, no other rationale is provided that would support such a conclusion as required to make a prima facie case of obviousness.

Contrastingly, Applicant submits that the disclosure of Smit indicates that making the device of Smit rigid would render Smit unsatisfactory for its intended purpose and change the principle of operation of Smit, which indicates that there is not a prima facie showing of obviousness (MPEP 2143.01, V and VI).

Smit specifically discloses that “because the walls of the tube (the extremely thin-walled tube 32) lack rigid support, the small intestine does not tend to gather itself and bunch up along the tube as often happens on catheters with thicker and more rigid tubes” (col. 5 lines 7-10). Smit continues on to expressly state that “it is not uncommon for the entire small intestine to gather itself along perhaps a three-foot section of fairly stiff tubing and then to pass any remaining tubing out the anus” (col. 5 lines 10-14). Smit concludes by indicating that “since tube 32 is balloon-thin and very supple it does not support the small intestine and, therefore prevents gathering of the intestine” (col. 5 lines 14-16).

Smit also discloses that “the tubular implant retains a very narrow or collapsed diameter when empty of food chemicals and expands outwardly as food chemicals enter” and continues on reciting “thus when the intestinal walls feel a change in diameter, they

commence peristaltic movements and contraction which squeeze the liquefied chime through the tubular implant and then out its open end” (col. 1 lines 26-32). Through this express disclosure Smit teaches the implant as a device that through its flexibility allows “normal peristaltic movements and contractions, in the patient’s body” (col. 1 lines 24-26).

Thus, Smit has provided at least two reasons that the tubular implant disclosed would not be rigid. The two reasons including prevention of the small intestine gathering on the implant and maintaining an implant that expands and contracts to maintain normal intestinal reactions to food.

Therefore, if Smit were modified by Crabb to be rigid gathering might occur and normal intestine reactions might be impeded, which would render Smit unsatisfactory for its intended purpose and would change the principle of operation of Smit.

As such, it would not have been obvious to one of ordinary skill in the art to modify the device disclosed by Smit to include rigid components as taught by Crabb.

Applicant submits that claim 31 is patentable over Smit in view of Crabb for at least the aforementioned reasons.

Wilkinson in view of Crabb

Claim 31 stands rejected under 35 U.S.C. 103 (a) as being unpatentable over Wilkinson USPN 5246456 in view of Crabb USPN 4315509.

The Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wilkinson to include rigid components as taught by Crabb. However, Wilkinson teaches a pouch that is both “flexible and expandable” and Applicant finds no disclosure in Crabb providing a rationale for making the flexible expandable pouch of Wilkinson rigid.

Additionally, the Examiner has not articulated any one of the seven rationales set forth in KSR as recited in MPEP 2143 nor any other rationale that provides support for the conclusion that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Smit to include rigid components as taught by Crabb.

The specific teaching of Wilkinson is to make the disclosed pouch out of high performance silicon elastomer having a durometer of 30 and imbedded “DACRON” tricot knit. Elastomers are generally a type of polymer having an elastic property. Wilkinson specifically recites that the elastomer used in the manufacture of the disclosed device has a durometer of 30, indicating that it is not hard or rigid.

Further, because the device of Wilkinson is in fact a stomach pouch that has to be secured around the patient's stomach and the pouch only includes a slot 28 for applying the pouch around a patient's stomach, it requires a degree of flexibility by design that would not be included if the device was rigid. Thus, making Wilkinson rigid would require a change in the basic principle under which the construction was designed to operate, rendering the modification non-obvious (MPEP 2143.01, VI). Wilkinson further demonstrates that the device is not intended to be rigid through his characterization of the device as **flexible** when he describes the device in claim 1 as “a hollow, **flexible** and thin-walled gastric pouch” col. 5 line 48).

Applicant submits that it would not have been obvious to one of ordinary skill in the art to modify Wilkinson, which explicitly discloses a flexible pouch, to be rigid in view of Crabb. Therefore, claim 31 is also patentable over Wilkinson in view of Crabb.

For the reasons set forth above, it is submitted that all pending claims are allowable over the art of record. Reconsideration of the claims and a notice of allowance are therefore requested.

### **Withdrawal of Claims**

Applicant objects to the Examiner's withdrawal of claims 19-29 and 33-36 and requests reconsideration of the withdrawn claims.

Claims 19-29 and 33-36 are encompassed by the elected invention because a storage that is bellow-like or adjustable may be consistent with a rigid storage. A storage that is rigid may, in certain circumstances, also be bellow-like or adjustable. A structure that is adjustable or bellow-like may still be rigid if, for example, means are provided that will maintain the adjustable or bellow-like structure in a rigid state. Such a device may be

adjusted to increase or decrease in size via bellows and then the device may be fixed into a rigid state via the provided fixing means, preventing further increasing or decreasing in size.

Therefore, Applicant submits that withdrawn claims 19-29 and 33-36 are encompassed by the elected species and requests that the Examiner withdraw the withdrawal of claims 19-29 and 33-36.

In addition, the applicant requests' that claims 37-40 be considered not withdrawn as they are consistent with the Applicant's election of the "rigid" species.

If the examiner has any questions, please feel free to contact the undersigned at (617) 443-9292.

Respectfully submitted,  
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